

## Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were completed in December 2015.

### Original Approvals

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This section displays the original approval. To read the complete approval, please refer to 21 CFR Parts 500 and the related Federal Register notices.

#### NADA Number: 141-453

Trade Name: hLAL rDNA construct in SBC LAL-C chickens  
Sponsor: Alexion Pharmaceuticals, Inc.  
Approval Date: December 8, 2015  
Species: Domesticated chickens  
Indications: Production of recombinant human lysosomal acid lipase (intended for use in humans) in egg whites of genetically engineered chickens.

### Supplemental Approvals

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This section displays the change(s) to the original approval. To read the complete approval, please refer to 21 CFR Parts 500 and the related Federal Register notices.

#### NADA Number: 141-258

Trade Name: Zilmax®  
Ingredients: Zilpaterol hydrochloride  
Sponsor: Intervet, Inc.  
Approval Date: December 2, 2015

This supplement provides for the replacement of the previously approved determinative and confirmatory procedures for cattle liver with new LC-MS/MS methods, addition of determinative and confirmatory procedures for cattle muscle, and inclusion of a tolerance of 10 ppb for zilpaterol in cattle muscle.

#### NADA Number: 141-361

Trade Name: Pulmotil® AC  
Ingredients: Tilimicosin phosphate  
Sponsor: Elanco Animal Health, A Division of Eli Lilly & Co.  
Approval Date: December 7, 2015

This supplement provides for a new indication for the control of swine respiratory disease (SRD) associated with *Mycoplasma hyopneumoniae* in the presence of Porcine Reproductive and Respiratory Syndrome Virus (PRRSV) in groups of swine in buildings where a respiratory disease outbreak is diagnosed.

### Medical Gases

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The following requests for certification of medical gases as designated medical gases were deemed to be granted:

Application Number	Sponsor Name	Medical Gas
141-350	Air Liquide America Specialty Gases	Nitrous Oxide, USP
141-351	Air Liquide America Specialty Gases	Medical Air, USP
141-354	Air Liquide Industrial U.S. L.P.	Oxygen, USP
141-357	Air Liquide Industrial U.S. L.P.	Nitrogen, NF
141-358	Air Liquide Large Industries U.S. L.P.	Oxygen, USP

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Application Number	Sponsor Name	Medical Gas
141-359	Air Liquide Large Industries U.S. L.P.	Nitrogen, NF
141-362	Linde LLC	Carbon Dioxide, USP
141-363	Linde Gas North America LLC	Medical Air, USP
141-364	Linde LLC	Nitrogen, NF
141-365	Linde LLC	Oxygen, USP
141-366	Machine and Welding Supply Company	Medical Air, USP
141-367	Industrial Gas Distributors	Medical Air, USP
141-368	Purity Cylinder Gases, Inc.	Medical Air, USP
141-369	Norco, Inc.	Nitrogen, NF
141-370	WestAir Gases & Equipment, Inc.	Medical Air, USP
141-371	Linde Merchant Production, Inc.	Carbon Dioxide, USP
141-372	Linde Gas Puerto Rico, Inc.	Nitrogen, NF
141-373	Linde Canada LTD	Oxygen, USP
141-374	Linde Gas Puerto Rico, Inc.	Oxygen, USP
141-375	Norco, Inc.	Oxygen, USP
141-376	Scott-Gross Company, Inc.	Medical Air, USP
141-377	DuPuy Oxygen & Supply Company, Inc.	Medical Air, USP
141-379	Air Liquide America L.P.	Medical Air, USP
141-380	Air Liquide America L.P.	Nitrogen, NF
141-381	Airgas Merchant Gases, LLC	Nitrogen, NF
141-382	Airgas Merchant Gases, LLC	Oxygen, USP
141-383	Airgas USA, LLC	Helium, USP
141-384	Airgas USA, LLC	Medical Air, USP
141-385	Airgas Carbonic, Inc.	Carbon Dioxide, USP
141-386	Oxarc, Inc.	Medical Air, USP
141-387	Praxair, Inc.	Oxygen, USP
141-388	Praxair, Inc.	Nitrogen, NF
141-389	Praxair, Inc.	Helium, USP
141-390	Praxair, Inc.	Carbon Dioxide, USP
141-391	NexAir, LLC	Medical Air, USP
141-393	Aspen Air, US Corp	Oxygen, USP
141-394	Aspen Air, US Corp	Nitrogen, NF
141-395	Air Products and Chemicals, Inc.	Helium, USP
141-396	Air Products and Chemicals, Inc.	Oxygen, USP
141-397	Air Products and Chemicals, Inc.	Nitrogen, NF
141-398	Air Liquide America L.P.	Oxygen, USP
141-399	Matheson Tri-Gas, Inc.	Oxygen, USP
141-400	Matheson Tri-Gas, Inc.	Medical Air, USP
141-401	Matheson Tri-Gas, Inc.	Nitrogen, NF
141-402	Praxair Distribution Inc.	Medical Air, USP
141-403	Praxair Distribution Mid-Atlantic, LLC	Medical Air, USP
141-404	Praxair Distribution Mid-Atlantic, LLC	Helium, USP
141-405	Praxair Distribution Inc.	Helium, USP
141-407	Praxair Canada Inc.	Nitrogen, NF
141-408	Praxair Canada Inc.	Oxygen, USP
141-409	United States Welding, Inc.	Medical Air, USP
141-410	Acetylene Oxygen Company	Medical Air, USP
141-411	Nitrous Oxide Corp	Nitrous oxide, USP
141-412	Nitrous Oxide of Canada	Nitrous oxide, USP
141-413	Airgas USA, LLC	Oxygen, USP
141-414	Airgas USA, LLC	Nitrogen, NF
141-415	Airgas USA, LLC	Carbon Dioxide, USP
141-416	Air Liquide Healthcare America Corporation	Helium, USP

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Application Number	Sponsor Name	Medical Gas
141-425	Linde Gas North America LLC	Helium, USP
141-428	Cee Kay Supply	Medical Air, USP
141-432	American Welding & Gas Inc.	Medical Air, USP
141-446	Strata Medical Innovations	Nitrous oxide, USP

### Sponsor Change

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#### (A)NADA Numbers: 200-342,

Previous: Bayer HealthCare LLC, Animal Health Division

New Sponsor: Farnam Companies, Inc.

Drug Labeler Code: 017135

### Patent Additions

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#### NADA Number: 141-434

Patent number: 9,168,251

Expiration Date: September 11, 2031

### Patent Deletions

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#### NADA Number: 141-177

Patent number: 5,502,222

Expiration Date: June 01, 2014

Patent number: 5,616,742

Expiration Date: May 22, 2015

Patent number: 5,750,745

Expiration Date: May 30, 2015

Patent number: 5,886,200

Expiration Date: June 25, 2017

### Withdrawal of Approval

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#### NADA Number: 140-680

Sponsor: Pharmgate LLC

Trade Name: Tylan® Premix

Ingredients: Tylosin phosphate

This product is withdrawn because the product is no longer manufactured or marketed.

#### NADA Number: 140-681

Sponsor: Pharmgate LLC

Trade Name: Tylan® Sulfa-G Premix

Ingredients: Tylosin phosphate and sulfamethazine

This product is withdrawn because the product is no longer manufactured or marketed.

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### **ANADA Number: 200-028**

Sponsor: Pegasus Laboratories, Inc.  
Trade Name: Evict®  
Ingredients: Pyrantel pamoate

This product is withdrawn because the product is no longer manufactured or marketed.

### **ANADA Number: 200-383**

Sponsor: Teva Canada Ltd.  
Trade Name: ClindaRobe™  
Ingredients: Clindamycin hydrochloride

This product is withdrawn because the product is no longer manufactured or marketed.

### **NADA Number: 007-616**

Sponsor: Zoetis Inc.  
Trade Name: Histostat® 50  
Ingredients: Nitarsone

This product is withdrawn because the product is no longer manufactured or marketed.

### **NADA Number: 141-088**

Sponsor: Zoetis Inc.  
Trade Name: Histostat® 50 plus BMD®  
Ingredients: Nitarsone and bacitracin methylene disalicylate

This product is withdrawn because the product is no longer manufactured or marketed.

### **NADA Number: 141-132**

Sponsor: Zoetis Inc.  
Trade Name: Histostat® 50 plus Albac®  
Ingredients: Nitarsone and bacitracin zinc

This product is withdrawn because the product is no longer manufactured or marketed.